

Claims

1. A composition of solifenacin or a salt thereof for use in solid formulation, the composition containing the crystal of solifenacin or a salt thereof, wherein the amorphous content is within a range showing no influence on product stability.

2. A composition of solifenacin or a salt thereof for use in solid formulation according to claim 1, wherein the amorphous content is 77 % or less.

3. A composition for use in solid formulation according to claim 1 or 2, which is produced by a manufacturing process including a step of blending solifenacin or a salt thereof with an excipient without using any solvent, followed by compressing-molding.

4. A composition for use in solid formulation according to claim 1 or 2, which is produced by a manufacturing process including a step of adding a solvent to solifenacin or a salt thereof, wherein the amount of solifenacin or a salt thereof to be dissolved per 1 mL of the solvent is less than 0.1 mg.

5. A composition for use in solid formulation

according to claim 4, wherein the solvent added to solifenacin or a salt thereof is acetone or hexane or a mixture thereof.

6. A composition for use in solid formulation according to claim 1 or 2, which is produced by a manufacturing process including a step of adding a solvent to prepare solifenacin or a salt thereof into an amorphous state, wherein the amount of solifenacin or a salt thereof to be dissolved per 1 mL of the solvent is 10 mg or more.

7. A composition for use in solid formulation according to claim 6, wherein the solvent to prepare solifenacin or a salt thereof into an amorphous state is water, methanol or ethanol or a mixture thereof.

8. A composition for use in solid formulation according to claims 1 through 7, which is manufactured by a manufacturing process including a step of promoting the crystallization of amorphous solifenacin or an amorphous salt thereof.

9. A mixture of solifenacin or a salt thereof, wherein the mixture contains amorphous and crystalline solifenacin or an amorphous and crystal salt thereof and wherein the amorphous content of solifenacin or a salt thereof is within a range

showing no influence on product stability.

10. A pharmaceutical composition for use in solid formulation, the composition containing crystalline and amorphous solifenacin or a crystalline and amorphous salt thereof, together with an inhibitor of amorphous preparation.

11. A pharmaceutical composition according to claim 10, wherein the inhibitor of amorphous preparation is a substance having ethylene oxide chain.

12. A pharmaceutical composition according to claim 11, wherein the substance with ethylene oxide chain is polyethylene glycol.